DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 2, 2015

Teleflex Medical Incorporated
Vladislava Zaitseva
Senior Regulatory Affairs Specialist, OEM
375 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K150438
Trade/Device Name: Force Fiber® OrthoTape™ Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: March 3, 2015
Received: March 4, 2015

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150438

Device Name
Force Fiber® OrthoTape™ Suture

Indications for Use *(Describe)*
Force Fiber® OrthoTape™ Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopaedic surgeries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

This 510(k) Summary for Teleflex Force Fiber® OrthoTape™ Suture is provided as required by section 807.92(c).

**Sponsor/Applicant:** Teleflex Medical Inc.
375 Forbes Boulevard
Mansfield, MA 02048 USA
FDA Establishment Registration #: 1221601

**Date Prepared:** March 31, 2015

**Contact:** Vladislava Zaitseva
Senior Regulatory Affairs Specialist, OEM
Phone: 1-508-964-6030
Fax: 1-508-964-6078
vladislava.zaitseva@teleflex.com

**Proprietary Name:** Force Fiber® OrthoTape™ Suture

**Common Name:** Polyethylene synthetic non-absorbable surgical sutures

**Classification Name:** Suture, nonabsorbable, synthetic, polyethylene

**Regulation Number:** 21CFR § 878.5000

**Product Code:** GAT

**Device Class:** Class II

**Classification Panel:** General and Plastic Surgery

## Device Description

Force Fiber OrthoTape suture is an uncoated braid offered in a variety of cut lengths, with or without needles, and provided sterile for single use only. Force Fiber OrthoTape suture is flat in shape and differs from USP requirements (not USP). It is available in 1mm, 1.5mm, 2mm, 2.5mm, 3.5mm, 4mm and 5mm tape sizes and composed of undyed or blue Ultra High Molecular Weight Polyethylene (UHMWPE), or UHMWPE/ Green Polyester co-braid. Force Fiber OrthoTape suture sizes meet USP tensile strength requirements and USP needle attachment requirements for USP size #2 suture.

**Indications for Use**
Force Fiber OrthoTape suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopaedic surgeries.

**Substantial Equivalence**
Force Fiber OrthoTape suture is substantially equivalent in intended use and fundamental scientific technology to the Force Fiber predicate devices cleared under 510(k) #K033654 on 1/15/2004, K063778 on 2/09/2007, K092533 on 9/15/2009, and K100506 on 3/10/2010.

**Technological Characteristics**
The substantial equivalence of Force Fiber OrthoTape suture is supported by having the same intended use, suture material, and equivalent design and performance characteristics to the previously cleared predicate device.

- **Intended Use/ Indications for use.** The modified Force Fiber OrthoTape suture is substantially equivalent in intended use to the Force Fiber predicate device.
- **Materials.** Modified Force Fiber OrthoTape suture and Force Fiber predicate suture device are composed of the same materials.
- **Sterilization processes.** Modified Force Fiber OrthoTape suture and Force Fiber predicate suture devices are sterilized using same sterilization processes conforming to recognized industry standards.
- **Performance specifications.** The test method used to confirm the performance specifications of tensile strength and needle attachment for both the proposed and predicate devices were conducted in accordance with USP requirements.

The differences between Force Fiber OrthoTape suture and its predicate devices include that Force Fiber OrthoTape suture has a different braiding configuration, which provides a flat in shape suture. Force Fiber OrthoTape suture does not comply with USP size classifications. These differences do not raise new questions of safety or efficacy. Therefore, Force Fiber OrthoTape suture is substantially equivalent to its currently marketed predicate devices.

**Summary of Testing**
Force Fiber OrthoTape suture is tested in accordance with USP - non-absorbable surgical sutures for tensile strength and needle attachment, and meet the requirements of the *Class II Special Controls Guidance: Surgical Sutures*; Guidance for Industry and FDA; June 3, 2003. All materials used in the fabrication of the Force Fiber OrthoTape suture were evaluated through biological qualification safety tests as outlined in AAMI ANSI ISO 10993-1: 2009/(R) 2013 -- *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*.

**Substantial Equivalence Conclusion**
Results from testing and engineering analyses provided within this 510(k) demonstrate that the Force Fiber OrthoTape suture is substantially equivalent to the identified predicate devices.